

REMARKS

Claims 1-57 are pending in the present application. Claims 15, 16, 20-47, 49 and 51-56, are canceled without prejudice or disclaimer as drawn to non-elected inventions. Applicants reserve the right to prosecute the subject matter of canceled claims 15, 16, 20-47, 49 and 51-56 in other divisional or continuation patent applications. Upon entry of the present amendment and reply, claims 1-14, 17-19, 48, 50 and 57 will be pending in the above-captioned application.

The Rejection under 35 U.S.C. § 112, Second Paragraph Should be Withdrawn

Claims 1-14, 17-19, 48, 50 and 57 are rejected under 35 U.S.C. § 112, second paragraph, as allegedly indefinite. On page 2 of the Office Action, it has been asserted that the phrase “immune response” recited in Claim 1 is vague. Applicants, respectfully, do not agree.

In response, Applicants first note that

Determining whether a claim is definite requires an analysis of whether one skilled in the art would understand the bounds of the claim when read in the light of the specification. If the claims read in light of the specification reasonably apprise those skilled in the art of the scope of the invention, § 112 demands no more. (*Solomon v Kimberly-Clark* 216 F.3d 1374, 1378 (Fed. Cir. 2000))

When viewed in the light of the present specification as filed, those of ordinary skill in the art would appreciate that the term “immune response” is used broadly and encompasses known forms of immunity that can be induced against an antigen. Such forms of immunity include cellular immunity, humoral immunity, and/or mucosal immunity, *i.e.*, immune responses that underlie *e.g.* prophylactic vaccination, therapeutic vaccination, and induction of long-term immunity to an antigen (*see* page 5, lines 2-4; page 13, lines 3-15; page 14, lines 8-11; and page 16, lines 9-12, of the application as filed).

In view of the specification as filed, those of ordinary skill in the art appreciate that modulation of an immune response according to the method of claim 1 includes the induction of humoral and mucosal immunity, which encompass production of antigen-specific antibodies, as demonstrated in Example 8 (Figure 11), Example 9 (Figure 13), Example 10 (Figure 14), Example 11 (Figure 15), Example 17 (Figure 22), Example 18 (Figure 23), Example 23 (Figure 32), and Example 24 (Figure 33), of the application as filed.

Similarly, in view of the specification as filed, those of ordinary skill in the art also appreciate that modulation of an immune response according to the method of claim 1 encompasses induction of cellular immune responses, which include production of antigen-specific cytotoxic T cells, as demonstrated in Example 6 (Figures 6, 7, and 8), Example 7 (Figures 9 and 10), and Example 16 (Figure 21), of the application as filed.

Those of ordinary skill would further appreciate that modulation of the “immune response” encompasses both the stimulation as well as the suppression of such cellular, humoral, and mucosal immune responses, or combinations thereof, against an antigen (*see e.g.*, page 5, lines 1-4; page 13, lines 3-15; and page 14, lines 8-11, as well as the original claims of the application as filed).

Applicants further submit that, in view of the specification as filed, those of ordinary skill in the art appreciate that the nature of the immune response (*e.g.* the stimulation or suppression of humoral, cellular and/or mucosal immune responses induced according to the method of claim 1 using a device of the present invention) is influenced by a number of factors including the immunogenicity, concentration, amount, and bioavailability of the particular antigen included within the matrix of the subject device (*see e.g.*, page 12, lines 1-6; page 15, lines 5-20; and page 24, lines 6-16, of the application as filed).

Those of ordinary skill in the art would further appreciate that the desired immune response can be achieved by exploiting and/or manipulating these factors while

using the device of the present invention. For example, those of ordinary skill in the art would be able to assess the immunogenicity of a particular antigen using *in vivo* and *in vitro* methods well known in the art and therefore readily determine the appropriate concentration of that antigen for stimulation or suppression of the immune response using a device of the present invention to achieve the desired effect (*see e.g.* page 15, lines 5-20, and page 24, lines 6-16 of the specification as filed).

Accordingly, those of ordinary skill in the art would understand that the method of claim 1 can be used to modulate (stimulate or suppress) *e.g.* cellular, humoral, and/or mucosal immune responses to an antigen in order to achieve a desired effect. That is, those of ordinary skill would understand that the term “immune response” is used broadly and therefore indicates that the method of claim 1 can be used to induce or suppress any desired immune response to a particular antigen using a device according to the present invention.

Consequently, Applicants respectfully submit that, in view of the above, the phrase “immune response” is not vague and that claim 1, in view of the specification as filed, reasonably apprises those of ordinary skill in the art of the scope of the invention defined by claim 1. Therefore, in view of the specification as filed, those of ordinary skill in the art would understand the bounds of claim 1, as well as those of independent claim 57 (which also recites the phrase “immune response”), and dependent claims 2-14, 17-19, 48, and 50, which depend, ultimately, on claim 1. Consequently, Applicants respectfully submit that independent claims 1 and 57, as well as claims 2-14, 17-19, 48 and 50 which depend on claim 1, are not indefinite. Accordingly, Applicants respectfully request that the rejection of claims 1-14, 17-19, 48, 50, and 57 as indefinite under 35 USC § 112, 2nd paragraph, be withdrawn.

CONCLUSION

Applicants believe that the ground for rejection of claims 1-14, 17-19, 48, 50 and 57 under 35 U.S.C. § 112, second paragraph has been successfully overcome, and therefore respectfully request that the rejection of claims 1-14, 17-19, 48, 50 and 57 under 35 U.S.C. § 112, second paragraph be withdrawn. Applicants submit that the entire application is now in condition for allowance, early notice of which would be appreciated. Should the Examiner not agree with Applicants' position, then a personal or telephonic interview is respectfully requested to discuss any remaining issues and expedite the eventual allowance of the application.

Respectfully submitted,

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